

REMARKS

The Final Official Action dated November 24, 2008 has been carefully reviewed. Claims 1-11 are pending in the subject application. Claim 12 has been previously canceled. Claims 1, 8, and 9 are amended herein.

SPECIFICATION

The Examiner noted the use of the trademark TEGADERM and OPSITE FLEXIGRID on page 10 of the present application. This is the only use of these trademarks and each is properly accompanied by generic terminology. As such, each use of the aforementioned trademarks within the specification of the present application is appropriate.

CLAIM OBJECTIONS

The Examiner objected to the use of the phrase “open at the top surface” in independent claims 1 and 9 as being redundant. While Applicants do not view this phrase as redundant, each of claims 1 and 9 is amended herein to instead recite that the discrete opening of claim 1 and the discrete holes of claim 9 are “uncovered at the top surface” to clarify that the discrete opening and the discrete holes are not covered or obstructed by any other structure or component of the claimed member for use in a vacuum bandage. In other words, the discrete opening recited in claim 1 and the discrete holes recited in claim 9 are each open, or uncovered, for direct communication with an undercut portion of a wound, for example. In view of this amendment to claims 1 and 9, withdrawal of the claim objections is respectfully requested.

§102 CLAIM REJECTIONS

The Examiner rejected claims 1-3 and 8 under 35 U.S.C. §102(b) as being anticipated by GB 2,329,127 to Heaton et al. (hereinafter Heaton). In making this rejection, the Examiner stated the following at pages 3 and 4 of the 11/24/08 Official Action:

Claim 1 now also requires the at least one discrete opening extending through a top surface of the cover be open at the top surface such that negative pressure is communicated to an undermined portion of the wound through the at least one discrete opening. It is noted however that such language does not require direct communication to the portion of the wound, i.e. does not require the opening to be directly open to the undermined portion, e.g. the opening having no structure over/connected over it or about it, i.e., and aperture through a surface which has a connector /structure located above it/around it is still open at the surface, e.g. open to the connector/structure.”

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Thus, a reference does not anticipate a claim if the claim contains any limitation that is neither literally nor inherently present in that reference.

Independent claim 1 is amended herein to recite that “the at least one discrete opening is *uncovered* at the top surface and *configured to be directly open to an undermined portion of the wound* such that negative pressure is communicated to the undermined portion of the wound *directly from* the at least one discrete opening.” Nowhere does Heaton disclose or suggest an opening “extending through a top surface of the cover” which is also “uncovered at the top surface and configured to be directly open to an undermined portion of the wound” in order to directly communicate negative pressure thereto.

As noted by the Examiner, the flange portion 30 of Heaton includes an aperture 34 and a connector 35 located above the aperture 34 for receiving and connecting a catheter thereto. The aperture 34 is in fluid communication with the tubular portion 36 of the connector 35 which is coupled to a source of suction in order to apply negative pressure to the wound. Aperture 34 is the only opening through a top surface in the flange portion 30. However, the aperture 34 of Heaton is not “uncovered at the top surface.” Rather, as noted above, the connector 35 is positioned above the aperture 34 to provide communication between the negative pressure source and the aperture 34. In other words, the aperture 34 is closed or covered at the top surface of the flange portion 30 and can, in no way, be “configured to be directly open to an undermined portion of a wound”, as is now recited in claim 1.

Furthermore, the aperture 34 does not and is not able to *directly* communicate negative pressure to an undermined portion of the wound because the aperture 34 of Heaton is covered and is not exposed to any wound surface, undermined or otherwise, to communicate negative pressure thereto. Rather, the aperture 34 of Heaton is provided to *receive* negative pressure from the vacuum source and not to communicate negative pressure to any portion of the wound *directly* from the aperture 34 itself. As such, while Heaton may disclose the use of foam pack to pack a wound cavity (via the WO 96/05873 publication incorporated by reference therein), Heaton does not disclose or suggest any cover “coupled to the wound contacting layer” which also includes “at least one discrete opening extending through a top surface of the cover . . . [that is] uncovered at the top surface and configured to be directly open to an undermined portion of the wound such that negative pressure is communicated to the undermined portion of the wound directly from the at least one discrete opening” as is recited in amended claim 1.

Accordingly, because Heaton does not disclose each of the elements reciting in claim 1, Heaton does not anticipate claim 1. As such, withdrawal of this rejection as it applies to claim 1, as well as claims 2 and 3, depending either directly or indirectly from of claim 1, is respectfully requested.

In regards to independent claim 8, the Examiner stated that “[i]t is noted that the claim does not require that the entire surface which faces the wound contactable layer be generally planar.” See page 6 of the 11/24/08 Official Action.

Independent claim 8 is amended herein to recite that the cover includes “a *generally continuous planar bottom surface which extends between an outer perimeter of the cover*, wherein approximately the *entire* generally continuous planar bottom surface is *directly* engaged with the top surface of the wound contactable layer.” Heaton does not disclose or suggest any cover having a generally continuous planar bottom surface which is also directly engaged with the top surface of the wound contactable layer. Rather, the flange portion 30 includes a series of projections 32 extending downwardly therefrom which contact the foam pad 73, as shown in FIG. 7 of Heaton. As such, while the flange portion 30 of Heaton may be generally planar, the entire flange portion 30, or any

part of the flange portion 30 for that matter, is certainly not directly engaged with the top surface of the foam pad 73 of Heaton. Furthermore, while each projection 32 of Heaton may have a generally planar bottom surface, such projections 32 certainly do not define *a generally continuous planar bottom surface* which extends between the outer perimeter of the flange portion 30 of Heaton. Accordingly, because Heaton does not disclose each of the elements recited in claim 8, Heaton does not anticipate 8. As such, withdrawal of this rejection as it applies to claim 8 is respectfully requested.

The Examiner rejected claims 1, 2, and 4-7 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,752,794 to Lockwood et al. (hereinafter Lockwood). As noted above, independent claim 1 is amended herein to recite that “the at least one discrete opening is *uncovered* at the top surface *and configured to be directly open to an undermined portion of the wound* such that negative pressure is communicated to the undermined portion of the wound *directly from* the at least one discrete opening.” Nowhere does Lockwood disclose or suggest an opening “extending through a top surface of the cover” which is also “uncovered at the top surface and configured to be directly open to an undermined portion of the wound” in order to communicate negative pressure to the undermined portion of wound *directly from* such an opening. As noted by the Examiner, the cover 52 of Lockwood includes a port (or hole) 51 coupled to a vacuum/irrigation tube 13, as shown in FIG. 3, and alternatively may include multiple ports which are also each coupled to a tube 70, as shown in FIG. 15. These holes 51 through the cover 52 of Lockwood are not “uncovered at the top surface.” Rather, because each hole 51 is coupled to a corresponding vacuum/irrigation tube 13 or 70, these holes 51 are clearly covered by such tubes 13, 70 and cannot be configured to directly open to an undermined portion of the wound. Furthermore, the holes 51 of Lockwood do not and cannot communicate negative pressure directly to an undermined portion of the wound because the holes 51 are covered and are not exposed to any wound surface, undermined or otherwise, to communicate negative pressure thereto. The holes 51 of the cover 52 of Lockwood are provided to *receive* negative pressure from the vacuum source and not to *directly communicate* negative pressure to any portion of the wound from the holes themselves. Therefore, Lockwood

does not disclose or suggest any “discrete opening” that is open, or uncovered, at the top surface of the cover and particularly does not disclose or suggest any cover which communicates negative pressure directly to an undermined portion of the wound through such an opening. Accordingly, because Lockwood does not disclose each of the elements reciting in claim 1, Lockwood does not anticipate claim 1. As such, withdrawal of this rejection as it applies to claim 1, as well as claims 2 and 4-7, depending either directly or indirectly from of claim 1, is respectfully requested.

§103 CLAIM REJECTIONS

The Examiner rejected claims 4-7 and 9-11 under 35 U.S.C. §103(a) as being unpatentable over Heaton in view of PCT Publication No. WO 99/01173 to Ohmstede (hereinafter Ohmstede). In making this rejection, the Examiner references the Abstract of Ohmstede which states that a thickening [12] of the drainage system “is provided on the underside with one or more openings, which open into and cooperate with the openings in the plate-shaped member [11].” The Examiner then stated that “[t]o make the one opening of the suction head/plate shaped member of ‘127 more than one opening would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by ‘173.” See page 11 of the 12/20/07 Office Action.

As noted in the Response filed March 17, 2008, Applicants asserted then and continue to assert that the Examiner has provided no viable analysis whatsoever as to why the Examiner believes that a person of ordinary skill in the art would combine Heaton and Ohmstede. Thus, the Examiner has failed to engage in the explicit analysis required by *KSR* and has failed to establish a proper obviousness rejection based on Heaton in view of Ohmstede.

Furthermore, in addition to the fact that the combination of Heaton and Ohmstede is improper, such a combination does not arrive at the invention recited in newly amended claim 9. Claim 9 recites “a second plurality of discrete holes opening through a top surface of the cover *and which are uncovered at the top surface*” and “the second plurality of discrete holes and the plurality of peripheral access channels adapted to communicate negative pressure *directly* to an undermined portion of the wound.” Emphasis added. Nowhere does Heaton disclose or suggest “a second

plurality of discrete holes opening through a top surface of the cover and which are uncovered at the top surface . . . [to] communicate negative pressure directly to an undermined portion of the wound.” Ohmstede, which Applicants assert above is not properly combinable with Heaton, does not make up for this deficiency. Nowhere does Ohmstede disclose or suggest “a second plurality of discrete holes opening though a top surface of the cover and which are uncovered at the top surface” in order to “communicate negative pressure directly to an undermined portion of the wound.” Ohmstede discloses a thickening 12 having openings formed in a bottom surface thereof, and a plate-shaped member 11 is coupled to the bottom surface of the thickening 12, as shown in FIG. 1 of Ohmstede, and includes openings 20 formed therethrough which are exactly aligned with the openings of the thickening 12. Accordingly, all openings 20 of the Ohmstede drainage system are closed openings which are not “uncovered at the top surface . . . [to] communicate negative pressure directly to an undermined portion of the wound.” Each of the holes 20 of the plate 11 is covered by the thickening 12 and is unable to communicate negative pressure directly to any portion of a wound surface. In other words, the holes 20 receive negative pressure from a suction unit 26 coupled to the thickening 12 through a tube 24 and communicate this negative pressure to the foam 23 below. However, the holes 20 do not and cannot communicate this negative pressure *directly* to a wound surface because they are covered and are not “uncovered at the top surface” as is recited in claim 9. Accordingly, the combination of Heaton and Ohmstede does not arrive at the combination of elements recited in claim 9. Withdrawal of this 35 U.S.C. § 103(a) rejection of claim 9 as well claims 10 and 11, depending either directly or indirectly from claim 9, is respectfully requested.

In regards to claims 4-7, each of these claims depends either directly or indirectly from independent claim 1 and incorporates all of the limitations of the base claim therein. As such, in view of the amendment made to claim 1 and the arguments set forth above in regards to claim 1, the rejection of dependent claims 4-7 is now moot. Furthermore, any arguments specific to claims 4-7 are held in abeyance without prejudice or admission to any assertion made by the Examiner in order to expedite prosecution. Accordingly, withdrawal of this rejection as it applies to claims 4-7 is respectfully requested.

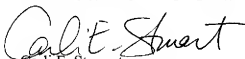
DOUBLE PATENTING

The Examiner rejected claims 1-2 and 4-7 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 30 of U.S. Patent No. 6,752,794 to Lockwood in view of Ohmstede PCT '173 and Heaton GB '127. As such, Applicants hereby submit herewith a Terminal Disclaimer in which the owner of the above-identified patent application disclaims the terminal part of the statutory term of any patent granted on the present application which would extend beyond the expiration date of the full statutory term of U.S. Patent No. 6,752,794 as outlined within the Terminal Disclaimer filed herewith.

FURTHER ACTION

In view of the foregoing remarks, the subject application is now deemed to be in condition for allowance, and such action is respectfully requested. If there are any questions or comments that would speed prosecution of this application, the Examiner is invited to call the undersigned at (317) 231-7216. It is respectfully requested that if necessary this paper be considered as a ONE-MONTH petition for an extension of time sufficient to effect a timely response and that any extension of time fees, as well as any other fees, be charged to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 7175-71858.

Respectfully submitted,
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